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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,418	12/19/2001	Himanshu Patel	018489-002510US	2779

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NT

Office Action Summary

Application No.

10/027,418

Applicant(s)

PATEL ET AL.

Examiner

Darwin P. Erez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-13, 32-39, 41, 42, 44-48, 62, 69-72 and 74-76 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 9-13 and 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39, 41, 42, 44-48, 62, 69-72 and 74-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 39, 41-32, 44-46, 48, 62, 69-72 and 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,643,296 to Hundertmark et al., and evidenced by US 5,429,136 to Milo et al.

As to claim 39, Hundertmark discloses in Figs. 10-14 a method of removing material (atherectomy) comprising the steps of: delivering a catheter having a tissue debulking device or cutter **138**; deflecting a distal portion of the catheter to a proximal portion of the catheter to expose the cutter; wherein the proximal movement of the catheter through a tortuous blood vessel causes the deflection (Fig. 11); and debulking the body lumen by rotating the cutter about an axis to expose the cutter through a cutting window **142** (transition from Fig. 10 to Fig. 12); and wherein catheter would inherently be advanced through the body lumen for further removal operations.

The step of advancing the catheter for further removal merely depends on the intended therapy for a particular patient since said patient could have more than one target site within the blood vessel (multiple obstructive tissues). Furthermore, the operation of Hundertmark's device within a tortuous region of the blood vessel does not require the inflation of the balloon, as seen in Figs. 11 and 12. Even so, the inflation of

the balloon does not "anchor" the device into the blood vessel. It merely biases the window portion of the catheter towards the obstructive tissues.

Furthermore, the Milo reference is being provided as evidenced that during an atherectomy procedure, it is well known in the art that the catheter may be repositioned to allow for further removal of obstructive tissue. A balloon may even be deflated and re-inflated to allow for said repositioning (col. 10, lines 4-7).

As to claim 41, Hundertmark teaches the cutter sliding through a groove or cam surface **185**.

As to claim 42, Hundertmark teaches the cutter rotating about the longitudinal axis of the catheter (Fig. 12).

As to claim 44, Hundertmark teaches a hollow nose cone **144** for packing or storing the severed material.

As to claims 45 and 48, Hundertmark teaches the deflection of the catheter occurring when the catheter is in a curved region of a blood vessel and the cutter is being urged against the tissue to be cut (moving the cutter from one position to the next position can occur simultaneously with the movement of the catheter).

As to claim 46, Hundertmark discloses a guidewire **146**.

As to claims 62, 69-72 and 74-76, Hundertmark discloses a method of debulking a body lumen comprising the steps of: providing a catheter having a rotating cutter **138**, a collection chamber **144**; a cutting window **142**; the cutter having a stored and exposed position (Fig. 10 or 1 and Fig. 11, respectively); wherein the cutter would be in the stored position prior to being placed within the body lumen; wherein the catheter has

means for rotating the cutter (col. 7, lines 17-20); exposing the cutter (Fig. 11); advancing the catheter to remove occlusive material while rotating the cutter (inherent in the operation of an atherectomy device); wherein the window is a side opening in the catheter (Fig. 10); and wherein the a drive shaft is connected to spline 130, which is then connected to a motor drive unit.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hundertmark in view of US 5,941,869 to Patterson et al.

Hundertmark teaches a method for cutting tissues within the vascular system of a patient but is silent with regards to using a cutter for removing tissues within a stent. However, Patterson teaches a method and device for cutting tissues, wherein a cutter is used to remove tissues within a stent (see Title and abstract). The device used in the method of Patterson is similar to the device used in the method of Hundertmark. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Hundertmark to remove tissues within a stent since it is well known in the art to use cutters to remove stenotic materials from stents, as taught by Patterson. It is also noted that Hundertmark discloses using a cutter to

remove tissue within a blood vessel, and that stents are normally located within blood vessels.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39, 41-42, 44-48, 62, 69-72 and 74-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-24 of copending Application No. 10/421979, claims 1-15 of copending Application No. 10/288581, claims 46-69 of copending Application No.

10/288559, and claims 1-11 of copending Application No. 10/288582. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the respective application's specifications discloses deflecting the distal portion relative to the proximal portion to reveal the cutter through the cutting window.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

6. Applicant's arguments filed 11/2/06 have been fully considered but they are not persuasive.

The applicant argued that the Hundertmark reference fails to disclose a device that is capable of being advanced through the body lumen because of the presence of a balloon. However, this is not persuasive because as seen in Figs. 11 and 12 of Hundertmark, the balloon is not inflated while in a tortuous region of the blood vessel. Furthermore, as cited in the rejection to claim 39 above, the balloon does not positively anchor the device onto the blood vessel to make it stationary. Instead, the balloon is merely used to bias the device towards the obstructive tissues.

With regards to the arguments that Hundertmark fails to teach a cutter movable between a stored position and an exposed position, it is noted that the location of the cutter in Fig. 1 is viewed as the stored position and that the location of the cutter in Figs 11 or 12 is viewed as the exposed position. The deflection of the distal end of the catheter exposes the cutter towards the obstructive tissues.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darwin P. Erez
Examiner
Art Unit 3731

de



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

